

DanuBalt:

**Novel Approaches in Tackling the Health Innovation and Research Divide in the
Danube and Baltic Sea Region**

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D3.1: Roadmap for the Baltic Sea regions in relation to the health sector

WP3, Tasks 3.1 - 3.3

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Abbreviations and Acronyms

Acronym	Description
BSR	Baltic Sea Region
D.3.1	Deliverable 3.1. (of Danubalt Project)
EC	European Commission
EU	European Union
EU2020	European Union 2020
EUSBSR	European Union Strategy for Baltic Sea Region
H2020	Horizon 2020
MS	Member State
PPP	Public Private Partnership
PPI	Public Procurement of Innovative Solutions
R&I	Research & Innovation
RDI	Research, Development and Innovation
PCP	Pre-Commercial Procurement
SMEs	Small and Medium sized Enterprises
WP3	Work Package 3 (of Danubalt Project)

Executive Summary

DanuBalt has been funded to analyse the mechanisms hindering the efficient exploitation of EU and regional instruments in the Baltic Sea and Danube macro regions as well as provide remedies that can help improve investment in regional health systems by efficiently using Structural Funds in combination with Horizon 2020.

The scope of WP3 (tasks 3.1 – 3.3) is to formulate *recommendations* for measures to widen participation and use synergies between European Funds (Structural Funds, H2020, PPP, etc.) and *propose action plans* for the Baltic Sea Region for setting up a tool for bridging innovation and providing a framework to plan and coordinate development. The recommendations present how these funds (programmes and investments) contribute to close the gap between “innovation leaders” and “modest innovators” and the roadmap shows how to explore synergies as well as existing and novel approaches and instruments in addition to the Structural Funds and H2020.

Based upon the consensus framework, four priorities critical for sustainable remedial actions have been identified with their relative enablers. The latter have been prioritised around *innovative public procurement*, *technology transfer* and *scaling up markets*.

This Roadmap was developed starting from the process described above, based on our previous results, a ***catalogue of tailor – made recommendations*** and an ***action plan*** including suggestions to remedial actions at EU/ regional level as how to alleviate the divide in R&I in Health domain. The action plan composed of seven actions at the regional level and further 4 measures to be taken at the EU level has been drafted.

The approach for the Roadmap development is based on the following content:

- Focus area (described at the beginning of this section)
- Goal of the Roadmap
- Specific objectives for each focus area
- Recommendation at regional and EU level
- Actions for each recommendation
- Action lines for each action
- Time frame (months), estimated costs or funding sources and target for each action line

Based on results of remedy/ validation phases new approaches tackling the divide will be implemented and the roadmap will be further updated / improved during 2nd implementation year (month 20) of DanuBalt.

Introduction

*“The divide between the research and innovation potential of the EU members states persists to be serious”¹. If we look at the level of **Health R&I performance** of the Member States even a more fragmented overall picture is discovered. Currently, the divide in research and innovation potential has regressed to 2009 performance levels with specific differences in scientific excellence, internationalisation and business innovation cooperation.*

DanuBalt proposed to “offer approaches specific to health research and innovation in the Danube and Baltic Sea Regions. [...] Analysing the 2 regions is not only interesting in terms of the huge regional coverage but also in relation of the potential of synergies as well as learning effect in avoiding past mistakes, discovering new venues and exploiting them”².

The main objective of DanuBalt is to explore novel pathways and integrate already proven approaches in addressing the divide between less performing RDI regions and lead innovating regions between and within the Danube and the Baltic Sea region.

In respect to above mentioned aspects, the main focus of DanuBalt is to:

- analyse the mechanisms hindering the efficient exploitation of European as well as Regional funding instruments in the Baltic sea and Danube macro- regions and
- offer remedies in order to improve investment in regional health systems by efficiently using Structural Funds in synergy with H2020.

The main objectives of WP3 are to:

- formulate recommendations for measures to widen participation and use synergies between funds, and
- develop Roadmaps for the Baltic Sea Region and the Danube Region for setting up a mechanism for bridging innovation and providing a framework to plan and coordinate development

The stakeholders from Health research and innovation participating at activities of DanuBalt represented health authorities, insurances entities, academia, laboratories, university clinics, research centres, SMEs, etc.

All DanuBalt partners participated at the implementation of WP3 and elaboration of deliverable D 3.1.

¹ DanuBalt Technical Annex, section 1.1.1. Background, page 2

² DanuBalt Technical Annex, section 1.3.3. Overall Approach, page 12

Methodology

After the identification of the essential conditions and critical requirements (facilitators) for Baltic Sea macro-region, a catalogue of tailor-made recommendations was formulated (using the findings of WP1 and validation of these findings in WP 2). The recommendations include suggestions to remedial actions at both EU and regional levels as to how to alleviate the divide in research and innovation in health sector.

The critical requirement scrutiny for each of the analyzed region (in this case the Baltic Sea Region) was used to provide the overall framework for the roadmaps. The roadmap report describes the overall framework, the critical factors and gives implementation recommendations at regional and EU level for the region.

The following describes how the methodology has been implemented within WP3:

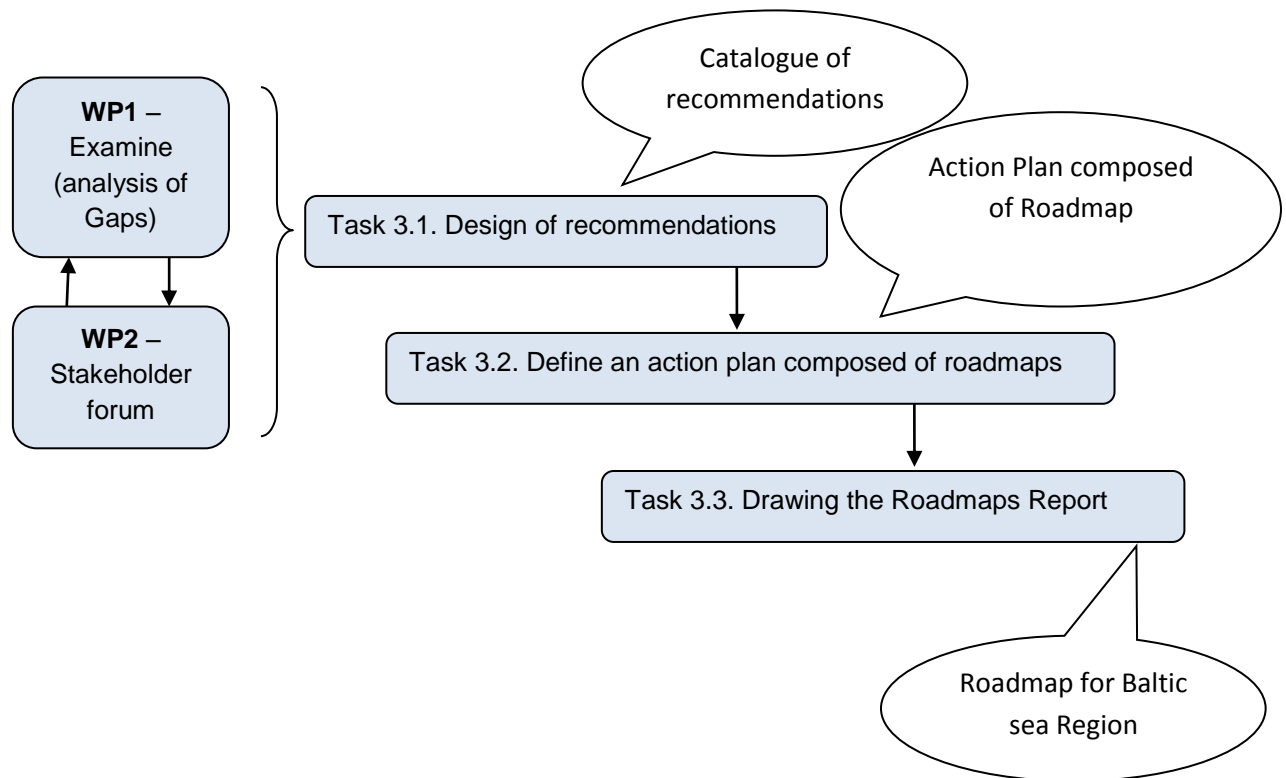


Figure 1 – The methodology supporting WP3 implementation

At the beginning, two types of **remedial actions** (denominated as **4 focus areas** in this report and presented in red below) were identified:

- a) **holistic improvements** focused on **redefining parameters for health care** among end-user health care providers and funders (this should be based on a whole systems approach);

b) 3 more specific **individual (but interrelated) actions** at regional and EU levels, acting as catalysts for improving performance in “modest” and “moderate” innovator regions, grouped into three categories:

- **HEALTH SERVICES**
- **TRANSLATIONAL RESEARCH AND INNOVATION**
- **SCALING UP MARKETS³**

For each of these three categories **one critical remedial action** has been identified, namely:

- Improving capacity and capability for more **transparent and informed procurement** of health innovation products by health care systems and providers (**innovative public procurement**);
- Support for more coherent and effective **translational research** along intraregional and cross-border value chains (**technology transfer**);
- **Health innovation markets** need expanding in smaller EU member states scaling up markets (**scaling-up markets**).

Specific actions at Regional and EU level were identified in order to show how the European, national and/or regional funds (programmes and investments) can contribute to close the gap between “innovation leaders” and “modest innovators” within the region.

³ See figure 2 of this report, page 11

1 Recommendations and Focus Areas

1.1 Critical remedial priorities and recommendations

After identification of essential conditions and critical requirements on Health R&I for the Baltic Sea Region, a catalogue providing **tailor-made recommendations** was prepared, based on the a) findings generated by **WP1** and b) validation of these findings (using *online survey* and the 3 *stakeholder fora* in **WP2**). Implementing these recommendations at the Baltic Sea regional level will be supported by use of the *consensus framework* for health innovation **enablers**⁴ (produced in WP1).

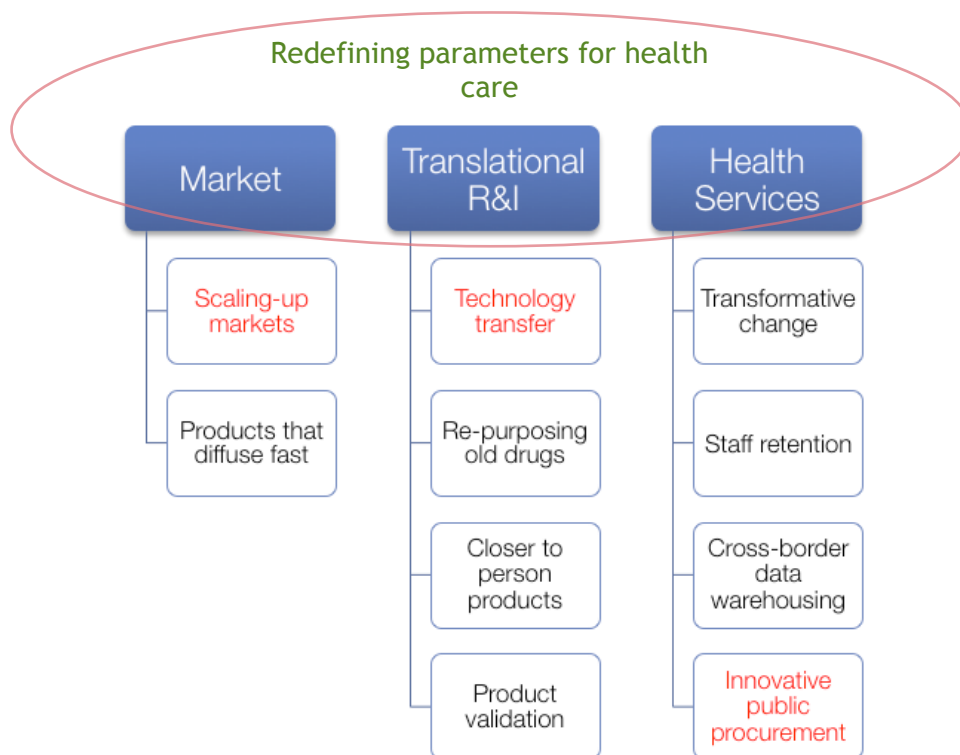


Figure 2 – Overview of critical remedial priorities

Two types of **remedial actions** are needed: a) **holistic improvements** focused on *redefining parameters for health care* among end-user health care providers and funders (this should be based on a whole systems approach) combined with b) more specific **individual (but interrelated) actions** at regional and EU levels.

⁴ Figure 2 presents the innovation enablers of the main importance validated by stakeholders participating at (3) fora;

These specific individual (but interrelated) actions at regional and EU level (highlighted in red in figure 2) are grouped in three categories: **Health services, Translational Research and Innovation and Markets** and have been selected in task 3.1 because analysis of the interview transcripts combined with conclusions from the 3 stakeholder fora (already organized during the 1st year of DanuBalt implementation) showed these three actions act as catalysts for improving performance in modest and moderate innovator regions, by:

- improving capacity and capability for more **transparent and informed procurement** of health innovation products by health care systems and providers (**innovative public procurement**);
- ensuring support for more coherent and effective **translational research** along intraregional and cross-border value chains (**translational R&I**);
- **scaling up markets** for health innovation products generated in modest and moderate innovator regions (**scaling-up markets**).

All recommendations, both at EU as well as Regional level, are presented within the full report (internal deliverable of task 3.1) entitled “**Catalogue of tailor-made recommendations**”; the report comprises specific *key messages* for each remedial action and general recommendations.

1.2 Action plan composed of roadmap

The headlines of the **actions plans** (proposed in task 3.2) correspond to the **remedial actions** identified in “**Catalogue of recommendations**” (task 3.1.) and are in this report denominated as **focus areas**, those being:

1. Redefining parameters for health care

As models of care evolve and needs change, there is a need to bridge existing cross-sectorial gaps by involving key regional actors in the value chain of health care innovations.

The main objective is to support the creation of sustainable, cost-effective, citizen centric healthcare systems promoting new jobs and businesses.

2. Innovative public procurement (IPP)

PPI, PCP and related initiatives for leveraging better public procurement (e.g. the EIP Smart Cities and Communities) need to be made better known among decision makers and public buyers. Good examples of transparent methods of procurement should be disseminated and valorized.

The main objective is to facilitate the access of new innovative products and services into the health care systems.

3. Technology transfer (TT)

National and regional health authorities and policy makers need to get to know and eventually use existing good examples of supporting translational research processes and dedicating a part of available financial support to business creation along the translational research pathway.

The main objectives are to bridge the gap between academia and industry in health and promote shared use of knowledge and innovation structures and universities.

4. Scaling up markets

Health innovation markets need expanding in smaller EU member states possibly in the form of geographic clusters (A = Latvia, Lithuania, Estonia), (B = Slovenia, Slovakia, Croatia with Hungary). One means for doing this is to support cross-border value chains that engage all stakeholders in the translational research continuum in parallel to using a compatible 'Living Labs' approach to facilitate local understanding and adoption.

The main objective is to promote the Baltic Sea Region as one test and development site for health care products and services.

In addition is included a basic pre-condition "**Knowing the region**" where recommended actions are mainly based on the practical experiences gained in ScanBalt BioRegion since 2001 and described in "**Models and Concepts for Shared Tools and Services between Regions and Clusters**".

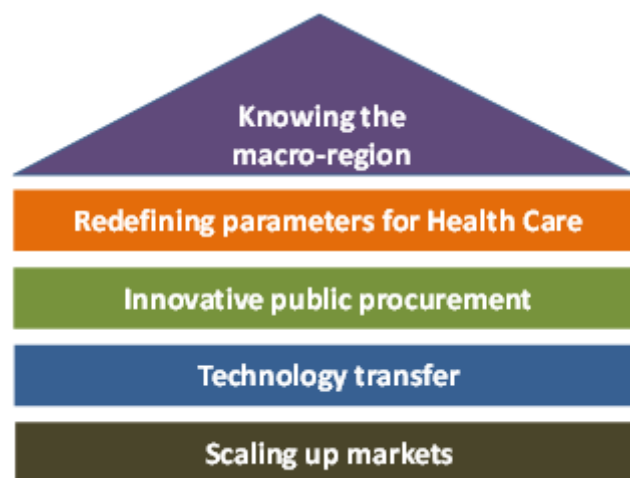


Fig 3: Overview remedial actions

To each focus areas is proposed a set of **recommended concrete regional actions** (for respectively the Baltic Sea Region) thereby bringing “*Catalogue of recommendations*” to the operative level. The operative level is to some extent additionally inspired by the practical experiences being described in “**Models and Concepts for Shared Tools and Services between Regions and Clusters**”. The use of Focus Areas and Actions aligns with the terminology applied in the **macro-regional strategy for health and life sciences in the Baltic Sea Region**⁵.

The whole report (internal deliverable of task 3.2.) entitled “**Action Plan for bridging the divide in the Health Innovation and Research in the Danube and Baltic Sea region**”, comprise specific actions per each of 4 remedial actions, time frame, funding sources and monitoring aspects.

⁵ ScanBalt Strategy 2015 - 2018: Solving societal challenges on Top of Europe, <http://scanbalt.org/about+scanbalt/strategy>

2 Roadmap for the Baltic Sea Regions in relation to the health sector

Based on,

- a) *inputs obtained from stakeholders during WP1 and WP2 activities,*
- b) *other (existing and/or planned) related agreements/plans/strategies in Baltic sea region concerning development of RDI (including Health sector),*
- c) *previous experience of DanuBalt partners regarding development of action plans, as well as*
- d) *specific results of task 3.1 - Design of recommendations and*
- e) *task 3.2 – Define Action Plan composed of Roadmaps,*

a *Roadmap for Baltic Sea region in relation to the health sector* has been drawn.

2.1 The goal

The overall goal of the *roadmap for the Baltic Sea Regions in relation to the health sector* is to promote smart specialization. Smart specialization should prioritise domains, areas and economic activities where regions or countries have a competitive advantage or have the potential to generate knowledge-driven growth and to bring about the economic transformation needed to tackle the major and most urgent challenges for the society and the natural and built environment. To have a smart specialization strategy means to make choices for investment.

Therefore obviously smart specialization and coordination between funding are closely related to each other.

Baltic Sea Region specifics (& challenges)

Health Economy is a strategic choice towards a knowledge-based sustainable economy able to meet some of the grand societal challenges of the regions and the regional networks.

Demographic shift is a major engine of the healthcare sector throughout the **Baltic Sea Region (BSR)**. Every segment of the health sector across the entire region is currently growing. However the region also shares with the rest of the EU challenges like economic disparities and lack of cohesion between the (sub) regions.

In BSR a weak trans-national and trans-sectorial coordination of the whole innovation chain is impeding generation of innovative ideas by research, obstructing development of innovative ideas by SMEs and slowing down transfer of innovative products and services

A fragmented system of research and innovation shows weak internal links and a low level of cooperation between actors.

In the medium and long term, the Baltic Sea Region is among the most dynamic healthcare markets in Europe. Healthcare spending in Poland and the Baltic States is growing at a disproportionately high rate and is fast approaching the average for Europe. For several years, the growth of employment in the health sector has been markedly more dynamic in the entire Baltic Sea Region than that of employment overall (except in Sweden)⁶.

Overall health economy in the Baltic Sea Region is intended to build on an Open Innovation Ecosystem. The main objective is to support the creation of sustainable, cost-effective, citizen centric healthcare systems promoting new jobs and businesses.

2.2 Objectives

In order to reach the goal of the roadmap, the following specific objectives have been established based on the **remedial actions** identified in “**Catalogue of recommendations**” (task 3.1.), described at the section 3.2 above.

- ✓ to support the creation of sustainable, cost-effective, citizen centric healthcare systems promoting new jobs and businesses;
- ✓ to facilitate the access of new innovative products and services into the health care systems
- ✓ to bridge the gap between academia and industry in health and promote shared use of knowledge and innovation structures and universities
- ✓ to promote the Baltic Sea Region as one test and development site for health care products and services.

2.3 Actions

Starting from the results of the previous WPs of DanuBalt combined with the above mentioned challenges⁷ of the Baltic Sea Region, the following **7 actions** have been proposed in order to present how these funds (programmes and investments) contribute to close the gap between “innovation leaders” and “modest innovators” and explore synergies as well as existing and novel approaches and instruments in addition to the Structural Funds and H2020.

- 1 **Overcome fragmentation at the policy level** (by setting-up a single body in the region that acts as a clearing-house for and curates good practice that connects the various policy

⁶ Based on: The Health Economy in the Baltic Sea Region: Challenges and Opportunities, ScanBalt Nov 2013, <http://scanbalt.org/files/graphics/Illustrations/BSR%20Health%20Economy.pdf>

⁷ which should be transformed into opportunities

areas: health, education, economy and finance as well as agriculture, environment and/or regional development);

- 2 **Improve the competencies of health care supply chain management and staff in making procurement decisions** regarding health innovation products. Specifically, in understanding the purpose, efficacy and quality of new health innovation products informed by health technology assessments.
- 3 **Raise awareness among procurement staff** that their role is not only about ensuring value for money in purchasing goods and services.
- 4 **Promote effective and coherent translational research pathways** to form effective regional and cross-border value chains;
- 5 **Set-up test and experimentation environments** where users and producers involved in regional and cross-border value chains can co-create innovations;
- 6 **Overcome barriers to data use** that limit access to datasets (life sciences and clinical) that can inform the need for products and testing innovations)
- 7 **Improve access to adequate market intelligence** about current and emerging products across the EU and so, identify market needs and what types of product could be considered both cutting edge and saleable.

These **seven proposed actions** addresses the 4 (four) focus areas defined in 3.2 above. Each action is addressed by one or more action lines, accompanied by stakeholders to be involved, a timeframe and estimated budget/sources of funding.

Additional 4 actions were also identified to be proposed at EU level, namely:

1. To **ensure separate and sufficient budget lines in EU Cohesion policies for macro-regions and their successful flagships** in order to fully exploit the potential of macro-regions and clusters as drivers for reaching key objectives of EU Cohesion Policies and the EU2020 strategy including Innovation Union;
2. **Development and implementation of transnational PPP** models for education;
3. **Enhance trans-national knowledge exchange and collaboration** between authorities, industry and academia in order to form a basis for lasting collaboration;
4. **To strengthen trans-national and cross-sectorial approaches** for launching projects and initiatives aimed at removing disparities, gaps and barriers in the EU and fostering cooperation within innovation in Health in order to overcome the grand societal challenges and bring innovative products and services to the market.

The actions were proposed as recommendations at Regional (chapter 4.4) as well as EU level (chapter 4.5.)

2.4 Recommendations at regional level

REMEDIAL ACTION: Redefining parameters for health care	
Key message	As models of care evolve and needs change, there is a need to bridge existing cross-sectoral gaps by involving key regional actors in the value chain of health care innovations. The main objective is to support the creation of sustainable, cost-effective, citizen centric healthcare systems promoting new jobs and businesses.
Action 1	<p><i>Overcome fragmentation at the policy level by setting-up a single body in the region that acts as a clearing-house for and curates good practice that connects the various policy areas: health, education, economy and finance as well as agriculture, environment and/or regional development.</i></p> <p>The main aim of this body should be to inform a very strong coordinated focus on the importance of the health economy for regional development (e.g. the Kuratorium Gesundheitswirtschaft des Landes Mecklenburg-Vorpommern).</p>
Action line	<p><u><i>Baltic Sea Region Health One-Stop</i></u></p> <p>In the Baltic Sea Region the non-profit association ScanBalt® fmba since 2004 (since 2001 as a project) has promoted smart specialization, coordinated investments and trans-national, cross sectorial project development across sectors but with health and life sciences as a common topic. ScanBalt emerged as a result of a demand not least from industry and the regions. Since 2009 it has been a flagship in EUSBSR (Health Region), Policy Area Innovation. The emergence of EUSBSR has led to a general fragmentation of activities due to opportunistic “fund hunt” without a wider perspective for BSR as most activities will not result in any sustainable structures but has also promoted successful policy oriented initiatives or initiatives which does not depart mainly from the innovation angle as ScanBalt does. In order to improve impact it would be beneficial to merge various health-oriented activities which have proven their worth, the capacity to mobilize regional/national investments for BSR collaboration otherwise not available and representing different levels from direct stakeholders to high level policy. A merger may be both activities oriented and organizational oriented depending on the progress in the discussions.</p>
Involved parties	ScanBalt, NDPHS, e-Health for Regions, EU, national and regional stakeholders etc.
Estimated time frame (months)	36 months
Estimated cost (euro)	<p>Annually round table discussions for 3 years between relevant organizations, decision and opinion makers (ScanBalt, NDPHS, e-Health for Regions, EU, national and regional stakeholders etc.):</p> <p>Room and catering for 3x1 day round tables/50 participants each: 12,500 EUR</p> <p>Travel of participants: 75,000 EUR</p> <p>Secretariat service, preparation of round tables 6 MM: 30,000 EUR</p> <p>Annual BSR Health Conference in connection with Round Tables: 100,000 EUR</p> <p>Health Economy State of the Region Analysis 6 MM: 30,000 EUR</p> <p><u>TOTAL: 247,500 EURO</u></p>

REMEDIAL ACTION: Innovative public procurement	
Key message	PPP, CPC and related initiatives for leveraging better public procurement (e.g. the EIP Smart Cities and Communities) need to be made better known among decision makers and public buyers. Good examples of transparent methods of procurement should be disseminated and valorized.
Action 1	<i>Improve the competencies of health care supply chain management and staff in making procurement decisions regarding health innovation products. Specifically, in understanding the purpose, efficacy and quality of new health innovation products informed by health technology assessments.</i>
Action line 1	<p><u>Change the behavior of health care management and staff</u></p> <p>Health care management and staff should be open and able to collaborate with industry in order to more efficiently solve major problems in healthcare. This involves mutual learning and learning e.g. from the processes of procurement and public-private collaboration like testing. It relates to a deeper understanding at the clinics of what is expected and needed by both themselves and the industry partner(s) in a public-private collaboration. The clinics should learn from each other's experiences and setups as well as through actual industry collaboration. Tools could be workshops, mutual learning and access to best practices (via e.g. study tours and visits).</p>
Involved parties	Health care management and staff, industry representatives
Estimated time frame (months)	24 months; This comprises identification and training of key staff members who can be catalysts and distribute the knowledge gained at their respective institutions plus dissemination at home institutions.
Estimated cost (euro)	<p>Room and catering for 12 x 1 day workshops/25 participants each: 25,000 EUR</p> <p>Travel of participants**: 150,000 EUR</p> <p>Travel of speakers 3 per workshop x 12 workshops: 18,000 EUR</p> <p><u>Total: 193,000 EUR</u></p> <p>*Cost do not include basic tasks like project management, auditing, dissemination etc as they are only estimates in order to prioritize</p> <p>**May be reduced if workshops are mainly regional and for regional participants</p>
Action 2	<i>Raise awareness among procurement staff that their role is not only about ensuring value for money in purchasing goods and services. They need support to understand the contribution that they can make to supporting the creation of sustainable, cost-effective,</i>

	<i>citizen centric healthcare systems promoting new jobs and businesses locally.</i>
Action line 1	<p><u>Introduction of new and better technologies</u></p> <p>Procurement staff should foster active participation in the introduction of new technologies into the clinical environment and assist to provide industrial access to clinical expertise. Therefore it is necessary to promote their understanding of innovation and the role of innovation for regional economy in addition with enhancing their knowledge about best practices. Tools could be workshops, mutual learning and access to best practices (via e.g. study tours and visits).</p>
Involved parties	Procurement staff in entities from health sector (SMEs, research centers, universities, clinics, hospitals, etc.)
Estimated time frame (months)	24 months; This comprises identification and training of key staff members who can be catalysts and distribute the knowledge gained at their respective institutions plus dissemination at home institutions.
Estimated cost (euro)	<p>Room and catering for 12 x 1 day workshops/25 participants each:25,000 EUR</p> <p>Travel of participants**: 150,000 EUR</p> <p>Travel of speakers 3 per workshop x 12 workshops: 18,000 EUR</p> <p><u>Total: 193,000 EUR</u></p> <p>*Cost do not include basic tasks like project management, auditing, dissemination etc. as they are only estimates in order to prioritize</p> <p>** May be reduced if workshops are mainly regional and for regional participants</p>

REMEDIAL ACTION: Technology Transfer	
Key message	National and regional health authorities and policy makers need to get to know and eventually use existing good examples of supporting translational research processes and dedicating a part of available financial support to business creation along the translational research pathway (the Harvard 'T' spectrum)
Action 1	<p><i>Promote effective and coherent translational research pathways to form effective regional and cross-border value chains.</i></p> <p>This is both affordable and sustainable if attention is given to the following:</p> <ul style="list-style-type: none"> • Utilising underused research infrastructure before investing in modest new infrastructure via ESIF, including value chain stakeholders sharing infrastructure resources; • Right-skilling basic researchers and clinical researchers to translate ideas into viable innovation products for testing and eventual commercialisation in partnership with industry – and especially local SMEs; • Provide financial support for SMEs and public health care providers to prepare 'proof of concept' for new innovation products • Organizational development that supports a culture of entrepreneurship that looks to

	better utilise resources and people skills in generating, adopting and diffusing innovation products
Action line 1	<p><u>Fighting hospital acquired infections and bacterial resistance with new diagnostic tools and services</u></p> <p>The World Economic Forum's Global Risks 2014 report includes antibiotic resistance among the top societal risks confronting the world. Additionally health systems are stressed due to demographic changes, cost effectiveness, rising consumer power and patient mobility. BSR has many well-experienced clinical study centers, a high number of companies with focus on infection control and is hosting some of the main European and global initiatives within antimicrobial resistance and hospital acquired infections. The action line will assist to bring down the infection levels by promoting uptake of new innovations in the health care systems. In particular SMEs struggle to have easy access to existing clinical infrastructure in order to validate diagnostic tools and services. It is currently often complicated to do so on a trans-national basis mainly due to different procedures and health care professionals need a positive attitude towards demand oriented product and process innovation.</p>
Involved parties	Clinicians, authorities, SMEs
Estimated time frame (months)	36 months
Estimated cost (euro)	<p>Regional workshops to identify needs of clinics: Room and catering for 12 x 1 day workshops/25 participants each: 25,000 EUR Travel of speakers 2 per workshop x 12 workshops: 12,000 EUR</p> <p>Trans-national workshops: Room and catering for 2 x 1 day workshops/25 participants each: 4,200 EUR Travel of speakers 2 per workshop x 2 workshops: 2,000 EUR Secretariat support preparation of workshops 6 MM: 30,000 EUR</p> <p>Dialogue between clinicians, SMEs and authorities: Room and catering for 12 x 1 day regional workshops/25 participants each: 25,000 EUR Travel of speakers 2 per workshop x 12 workshops: 12,000 EUR Secretariat support preparation of workshops 6 MM: 30,000 EUR Catalogue of regulatory aspects, authorities, activities, procedures 6 MM: 30,000 EUR Compendium of SME funding opportunities and IPR advice 4 MM: 20,000 EUR Situation analysis and best practices, cooperation of SMEs with clinics incl. indicators and standard operations procedures 4 MM: 20,000 EUR Idea competition for SMEs, 4 MM: 20,000 EUR 6 pilots supporting clinic-SME collaboration, coaching 18 MM: 90,000 EUR</p> <p>Online platform for communication between clinical needs and SME offers for solutions: Online platform development (subcontract, open tender): 25,000 EUR Develop, test and validate pilot cases 6 MM: 30,000 EUR Development of professional service options 6 MM: 30,000 EUR</p> <p>Total: 405,200 EUR</p>
Action 2	<p><i>Set-up test and experimentation environments where users and producers involved in regional and cross-border value chains can co-create innovations</i></p> <p>Identify innovation infrastructures that provide good validation opportunities for start-ups. Establish processes facilitating access for SMEs to health niche infrastructures in order to promote commercialization. Begin with validation centres ready to open up their services and</p>

	develop other centres based on best practices. There are two main activity lines: (1) Identify need based innovation (products, business models) by workshops in validation centres with students, developers, SMEs; (2) run validation process for start-ups in the validation centres with the target groups.
Action line 1	<p><u>Identify need based innovation (products, business models) by workshops in validation centres with students, developers, SMEs</u></p> <p>This should lead to improved management skills of the health innovation infrastructures (living labs/validation centres, incubators, accelerators, science parks); more efficient transnational utilisation of health innovation infrastructures (open for SMEs and developers from all BSR and specialized therefore complementary); improved opportunity for innovation infrastructures to become sustainable.</p>
Involved parties	Universities/centres with students, developers, SMEs;
Estimated time frame (months)	36 months
Estimated cost (euro)	<p>Room and catering for 12 x 1 day workshops/ 25 participants each: 25,000 EUR</p> <p>Travel of participants**: 150,000 EUR</p> <p>Travel of speakers 3 per workshop x 12 workshops: 18,000 EUR</p> <p><u>Total action line 1: 193,000 EURO</u></p> <p>*Cost do not include basic tasks like project management, auditing, dissemination etc. as they are only estimates in order to prioritize</p> <p>** May be reduced if workshops are mainly regional and for regional participants</p>
Action line 2	<p><u>Run validation process for start-ups in the validation centres with the target groups.</u></p> <p>This should lead to improved management skills of the health innovation infrastructures (living labs/validation centres, incubators, accelerators, science parks); more efficient transnational utilisation of health innovation infrastructures (open for SMEs and developers from all BSR and specialized therefore complementary); improved opportunity for innovation infrastructures to become sustainable.</p>
Involved parties	Universities/RDI centres having students, developers, SMEs;
Estimated time frame (months)	36 months
Estimated cost (euro)	<p>Identification of best practice in selected validation centres 2 MM: 10,000 EUR</p> <p>Development of transnational validation process 3 MM: 15,000 EUR</p> <p>Piloting validation process with 12 companies from partner regions 24 MM: 120,000 EUR</p> <p>Development of further validation centres for transnational use 12 MM: 60,000 EUR</p> <p>Fine-tuning of international validation process 2 MM: 10,000 EUR</p> <p>Entering collaboration with additional centres: 3 MM: 15,000 EUR</p> <p><u>Total action line 2: 230,000 EURO</u></p> <p>*Cost do not include basic tasks like project management, auditing, dissemination etc. as they are only estimates in order to prioritize</p> <p>** May be reduced if workshops are mainly regional and for regional participants</p>

REMEDIAL ACTION: Scaling up markets	
Key message	Health innovation markets need expanding in smaller EU member states possibly in the form of geographic clusters (Latvia, Lithuania, Estonia), (Slovenia, Slovakia, Croatia, Hungary). One means for doing this is to support cross-border value chains that engage all stakeholders in the translational research continuum in parallel to using a compatible 'Living Labs' approach to facilitate local understanding and adoption.
Action 1	<i>Overcome barriers to data use that limit access to datasets (life sciences and clinical) that can inform the need for products and testing innovations.</i> Specifically, this means changing organisational mindsets that ignore management and staff behaviour where control of information is power and a means for maintaining relevance in health care systems that need to transform and modernize.
Action line 1	<u>Shared data platform</u> The various countries' health information technology capacity (e.g. large image databanks, phenotype data collection and exchange) and research infrastructures (e.g. bio-banks) are very well advanced. Combined with existing national infrastructures (e.g. electronic authentication) it generates opportunities for the development of services which can benefit individuals, reduce public health care spending and promote SME and industry based innovation. One of the issues to be tackled is enabling the cross-border and cross-database use of health data and images (compatibility, technical, ethical and legal compliance). Establish a common platform enabling cross-border use of existing research infrastructures for data search and data exchange handling. Involve piloting SMEs obtaining proof of concept for their services based on the project platform.
Involved parties	Information technology centers, research centers & infrastructures, authorities
Estimated time frame (months)	36 months
Estimated cost (euro)	<p>Technical (including standards), legal, ethical, and organizational detailed analysis and feasibility study 12 MM: 60,000 EUR</p> <p>Room and catering for 6 x 1 day workshops/25 participants each: 12,500 EUR</p> <p>Travel of participants**: 75,000 EUR</p> <p>Travel of speakers 3 per workshop x 6 workshops: 9,000 EUR</p> <p>Secretariat support 3 MM: 15,000 EUR</p> <p>Establish agreement on main functionalities, aims, governance structure, management and usage of the common platform:</p> <p>Room and catering for 6 x 1 day workshops/25 participants each: 12,500 EUR</p> <p>Travel of participants**: 75,000 EUR</p> <p>Travel of speakers 3 per workshop x 6 workshops: 9,000 EUR</p> <p>Secretariat support 6 MM: 30,000 EUR</p> <p>Online platform development (subcontract, open tender): 100,000 EUR</p> <p>Develop, test and validate 5 pilot services based on online platform 15 MM: 75,000 EUR</p> <p>Total: 473,000 EUR</p> <p>*Cost do not include basic tasks like project management, auditing, dissemination etc as they are only estimates in order to prioritize</p> <p>** May be reduced if workshops are mainly regional and for regional participants</p>

Action 2	<p><i>Improve access to adequate market intelligence about current and emerging products across the EU and so, identify market needs and what types of product could be considered both cutting edge and saleable.</i></p> <p>Two options for achieving market penetration in this context should be:</p> <ol style="list-style-type: none"> 1. Buying from the stock of failed drugs which could be repositioned if optimal responders are properly characterized 2. Creating new products that offer prevention, risk management and monitoring rehabilitation functions that are 'closer to patients' and less invasive than products currently used in clinical and primary care settings
Action line 1	<p><u>Action line: Market analysis</u></p> <p>A market analysis should</p> <ol style="list-style-type: none"> (1) Identify prevailing economic, social and geographic conditions in the BSR area as the engine of the healthcare sector; (2) Identify discrepancies in states of health and life expectancy; (3) Identify common societal challenges like obesity, AMR, eating habits and reveal discrepancies within the Danube area; (4) Convergence of healthcare systems and their future challenges; (5) Analyze growth of the healthcare sector country wise identifying particular interesting growth sub-sectors; (6) Describe the healthcare sector in the context of the innovation system of the BSR area; (7) Identify initiatives promoting open innovation and collaborative approaches in health care.
Involved parties	Consultancy, healthcare stakeholders, authorities
Estimated time frame (months)	12 months
Estimated cost (euro)	<p>Identify prevailing conditions 1 MM: 5,000 EUR</p> <p>Identify discrepancies 1 MM: 5,000 EUR</p> <p>Identify common societal challenges 0,5 MM: 2,500 EUR</p> <p>Identify convergence of health care systems 1 MM: 5,000 EUR</p> <p>Analyze growth of the healthcare sector country wise 6 MM: 30,000 EUR</p> <p>Describe the healthcare sector 1 MM: 5,000 EUR</p> <p>Identify initiatives 1 MM: 5,000 EUR</p> <p>Total: <u>57,500 EUR</u></p> <p>*Cost do not include basic tasks like project management, auditing, dissemination etc. as they are only estimates in order to prioritize</p>

2.5

Recommendations at EU level

REMEDIAL ACTION: Redefining parameters for health care	
Key message	As models of care evolve and needs change, there is a need to bridge existing cross-sectorial gaps by involving key regional actors in the value chain of health care innovations. The main objective is to support the creation of sustainable, cost-effective, citizen centric healthcare systems promoting new jobs and businesses.
Action 1	To ensure separate and sufficient budget lines in EU Cohesion policies for macro-regions and their successful flagships in order to fully exploit the potential of macro-regions and clusters as drivers for reaching key objectives of EU Cohesion Policies and the EU2020 strategy including Innovation Union
Action line	Sustainability of macro-regional initiatives
Involved parties	Macro-regional flagships
Estimated time frame (months)	To follow EU budget periods
Estimated cost (euro)	100,000 EUR/Year/flagship

REMEDIAL ACTION: Innovative public procurement	
Key message	PPP, CPC and related initiatives for leveraging better public procurement (e.g. the EIP Smart Cities and Communities) need to be made better known among decision makers and public buyers. Good examples of transparent methods of procurement should be disseminated and valorized.
Action 1	Development and implementation of transnational public-private partnership models for education
Action line 1	Transnational public-private partnership in education between universities and industries should be promoted (learn from the best). The intentions are to strengthen coordinated trans-national public-private education in health procurement by involvement of regions, clusters, institutions and industries throughout and between macro-regions
Involved parties	Public authorities, knowledge institutions, industries
Estimated time frame (months)	Minimum 3 years trial period
Estimated cost (euro)	N/A

REMEDIAL ACTION: Technology Transfer	
Key message	National and regional health authorities and policy makers need to get to know and eventually use existing good examples of supporting translational research processes and dedicating a part of available financial support to business creation along the translational research pathway (the Harvard 'T' spectrum)

Action 1	Enhance trans-national knowledge exchange and collaboration between authorities, industry and academia in order to form a basis for lasting collaboration
Action line 1	Development of an EUSBSR Venture Capital Fund in order to increase transnational innovation activities
Involved parties	National and regional health authorities and policy makes, industries, public-private investors
Estimated time frame (months)	Minimum 3 years
Estimated cost (euro)	To be discussed

REMEDIAL ACTION: Scaling up markets	
Key message	Health innovation markets need expanding in smaller EU member states possibly in the form of geographic clusters (Latvia, Lithuania, Estonia), (Slovenia, Slovakia, Croatia, Hungary). One means for doing this is to support cross-border value chains that engage all stakeholders in the translational research continuum in parallel to using a compatible 'Living Labs' approach to facilitate local understanding and adoption.
Action 1	To strengthen trans-national and cross-sectorial approaches for launching projects and initiatives aimed at removing disparities, gaps and barriers in the EU and fostering cooperation within innovation in Health in order to overcome the grand societal challenges and bring innovative products and services to the market.
Action line 1	Strengthen instruments which aim at the formation of new and the strengthening of existing regional research and innovation-driven (triple helix) clusters. Promoting regional knowledge triangle type cooperation by developing instruments supporting smart specialization between the clusters and supporting clusters to be linked together in complementary innovation chains in order to reach major EU objectives.
Involved parties	Regional authorities, SMEs, industries and knowledge institutions
Estimated time frame (months)	Minimum 3 years to have an effect.
Estimated cost (euro)	100,000 EUR/year/regional initiative

2.6 Time frame and costs (summary)

The proposed action lines may be packed together in concrete projects in many ways so a proposed action line is not equal to a project proposal (it may for example just be a work package within a project covering more than one remedial action).

The time frames are estimates based on various previous, ongoing or planned comparable project activities and previous experience of the members of DanuBalt consortium.

Costs for the various action lines do not include basic tasks like project management, auditing, dissemination or any other basic project costs. They only try to reflect costs of essential core activities and are only estimates. Costs for travels may in some cases be reduced if workshops are mainly regional or national.

✓ Proposed actions at regional level

Remedial action / Action lines	Time Frame (Months)	Cost estimate (EUR)
Redefining parameters for Health Care		
<i>BSR Health One-Stop</i>	36	247,500
Innovative public procurement		
<i>Training, Health care management and staff</i>	24	193,000
<i>Introduction of new technologies</i>	24	193,000
Technology transfer		
<i>Fighting hospital acquired infections</i>	36	405,200
<i>Test and experimentation environments</i>	36	423,000
Scaling up markets		
<i>Shared data platform</i>	36	473,000
<i>Market analysis</i>	12	57,500

✓ **Proposed actions at EU level**

Remedial action / Action lines	Time Frame	Source of funding
1. Redefining parameters for Health Care		
<i>Sustainability of macro-regional initiatives</i>	<i>To follow EU budget periods</i>	<i>100,000 EUR/Year/flagship</i>
2. Innovative public procurement		
<i>Transnational public-private partnership in education between universities and industries should be promoted (learn from the best). The intentions are to strengthen coordinated trans-national public-private education in health procurement by involvement of regions, clusters, institutions and industries throughout and between macro-regions</i>	<i>Minimum 3 years trial period</i>	<i>N/A</i>
3. Technology transfer		
<i>Development of an EU/BSR Venture Capital Fund in order to increase transnational innovation activities</i>	<i>Minimum 3 years</i>	<i>To be discussed</i>
4. Scaling up markets		
<i>Strengthen instruments which aim at the formation of new and the strengthening of existing regional research and innovation-driven (triple helix) clusters. Promoting regional knowledge triangle type cooperation by developing instruments supporting smart specialisation between the clusters and supporting clusters to be linked together in complementary innovation chains in order to reach major EU objectives</i>	<i>Minimum 3 years to have an effect</i>	<i>100,000 EUR/year/regional initiative</i>

2.7 Monitoring

Implementation of the Action Plan is overseen and monitored by ScanBalt® fmba. This takes place as part of an established process where project responsible each quartile reports at the ScanBalt board (ExCo) meeting.

In addition ScanBalt® fmba is actively involved in developing the Policy Area INNO impact logic and monitoring framework.

The monitoring framework has the following objectives:

- ✓ To signal the ambitions of the Strategic Action Plan (SAP) to all stakeholders
 - To ensure have right priorities and confirm commitment of MS
 - To provide a clear direction for the PA INNO flagships
- ✓ To provide a framework to track progress of the SAP – to ensure doing the right things and doing them in the right way
 - To ensure alignment between RIS3 strategies and flagships
 - To highlight where there are barriers/where do not make progress on given priorities
 - To track transnational dynamics (in terms of, for example, levels of participation or investment from different MS and actor groups)
- ✓ To enable more efficient and effective communication
 - To enable smooth and transparent reporting to the Commission
 - To ensure clarity and more effectively promote the work of PA INNO and its flagships

ScanBalt® fmba will thus have the responsibility to ensure that the monitoring is also reflected into the Policy Area INNO impact logic and monitoring framework.

3 Conclusion

This report summarizes the process that led to the elaboration of a first version of the “**Roadmap for the Baltic Sea Region in relation to the Health sector**” (comprising recommendations, actions, action lines, time frame, funding sources and stakeholder’s involvement).

The adopted systematic methodology has enabled well-focused discussions, both at the consortium level and during the first year interactions with stakeholders.

At the current stage there is already a good level of consensus inside the DanuBalt consortium regarding the proposed actions. The feedback from stakeholders on proposed actions will be obtained during the 2nd year of project activities (mainly through the pilot actions).

The methodology being followed, which was explained during the 3 fora to participants, also got a very good level of appreciation. Also, all the consortium members accepted the methodology.

One important aspect reflected in the actions is the aim to **overcome fragmentation at the policy level by connecting various policy areas at regional level** (such as health, education, economy and finance as well as agriculture, environment and/or regional development).

Another aspect is to **enhance the cooperation between academia and representatives of business environment / industry** in creation of sustainable, cost-effective, citizen centric healthcare systems.

A third aspect is that In BSR a weak transnational and trans-sectoral coordination of the whole innovation chain is impeding generation of innovative ideas by research, obstructing development of innovative ideas by SMEs and slowing down transfer of innovative products and services.

A fragmented system of research and innovation shows weak internal links and a low level of cooperation between actors.

Macro-regional concepts and regional clustering promoting health economy may be applied to:

- reduce disparities between the levels of development of the regions and enhance cohesion
- mobilize growth potential to achieve economic, social and territorial cohesion
- enhance investments in knowledge
- improve framework conditions

- reduce fragmentation
- avoid duplication
- address the grand societal needs and challenges directly with specific measures

As mentioned above, the Roadmap results will be tested in the 2 Pilot projects (WP4) concentrating around possible topics areas dealing with talent attraction, SME and Business services, education and entrepreneurship, idea competition and acceleration for transnational health projects. WP4 will elaborate and start implementing new approaches towards joined research and innovation activities in the two macro regions BSR and Danube. Moreover it will investigate on new joined activities of the two region. This will be based on the validated analyses and defined roadmaps of previous WPs.

Once the ongoing consultation and validation process ends (during the 2nd year of DanuBalt mplementation- month 20), this first version of the roadmap will be refined and subject to fine detailing (mainly through Wp4 activities – pilot actions).

Roadmap for the Baltic sea region in relation to health sector							
Focus Areas	Redefining parameters for health care	Innovative public procurement (IPP)	Technology transfer (TT)		Scaling up markets		
Goal	The goal of this roadmap is to offer remedies overcoming the barriers related to the fact that in BSR a weak transnational and trans-sectoral coordination of the whole innovation chain is impeding generation of innovative ideas by research and clinics, obstructing development of innovative ideas by SMEs and slowing down transfer of innovative products and services to the health care systems.						
Specific objectives	Support the creation of sustainable, cost-effective, citizen centric healthcare systems promoting new jobs and businesses;	Facilitate the access of new innovative products and services into the health care systems	Bridge the gap between academia and industry in health; Promote shared use of knowledge and innovation structures and universities		Promote the Baltic Sea region as one test and development site for health care products and services.		
Recommendations at REGIONAL level							
Actions	Overcome fragmentation at the policy level by setting-up a single body in the region that acts as a clearing-house for and curates good practice that connects the various policy areas	Improve the competencies of health care supply chain management and staff in making procurement decisions regarding health innovation products.	Raise awareness among procurement staff that their role is not only about ensuring value for money in purchasing goods and services.	Promote effective and coherent translational research pathways to form effective regional and cross-border value chains.	Set-up test and experimentation environments where users and producers involved in regional and cross-border value chains can co-create innovations	Overcome barriers to data use that limit access to datasets (life sciences and clinical) that can inform the need for products and testing innovations	Improve access to adequate market intelligence about current and emerging products across the EU
Action lines	Baltic Sea Region Health one- stop	Change the behavior (training) of health care management and staff	Introduction of new and better technologies	Fighting hospital acquired infections and bacterial resistance with new diagnostic tools and services	Identify innovation infrastructures that provide good validation opportunities for startups.	Shared platform data	Market analysis
Timeframe (months)	36	24	24	36	36	36	12

Estimated costs (euro)	247,500	193,000	193,000	405,200	423,000	473,000	57,500
Targets / deliverables	1 yearly round table discussions for 3 years between relevant organisations, decision and opinion makers (50 participants per event), Annual BSR Health Conference in connection with Round Tables	Identification of key staff to be trained, organisation of 12 training events for 25 participants (one day event)	Identification of key staff to be trained, organisation of 12 training events for 25 participants (one day event)	Organisatin of 12 regional workshops for 25 participants (one day event) Organisatin of 2 trans-national workshops for 25 participants (one day event) 6 pilots supporting clinic – SMEs collaboration one-line platform	Organisatin of 12 innovation trainings for 25 participants (one day event) Organisatin of validation process for startups	Feasibility study Establish agreement on main functionalities, aims, governance structure, management and usage of the common platform	Market analysis

Recommendations at EU level				
Focus Areas	Redefining parameters for health care	Innovative public procurement (IPP)	Technology transfer (TT)	Scaling up markets
Actions	To ensure separate and sufficient budget lines in EU Cohesion policies for macro-regions and their successful flagships in order to fully exploit the potential of macro-regions and clusters as drivers for reaching key objectives of EU Cohesion Policies and the EU2020 strategy including Innovation Union	Development and implementation of transnational public-private partnership models for education,	Enhance trans-national knowledge exchange and collaboration between authorities, industry and academia in order to form a basis for lasting collaboration	To strengthen trans-national and cross-sectoral approaches for launching projects and initiatives aimed at removing disparities, gaps and barriers in the EU and fostering cooperation within innovation in Health in order to overcome

				the grand societal challenges and bring innovative products and services to the market.
Action lines	Sustainability of macro-regional initiatives	Transnational public-private partnership in education between universities and industries should be promoted (learn from the best). The intentions are to strengthen coordinated trans-national public-private education in health procurement by involvement of regions, clusters, institutions and industries throughout and between macro-regions	Development of an EU/BSR Venture Capital Fund in order to increase transnational innovation activities	Strengthen instruments which aim at the formation of new and the strengthening of existing regional research and innovation-driven (triple helix) clusters. Promoting regional knowledge triangle type cooperation by developing instruments supporting smart specialisation between the clusters and supporting clusters to be linked together in complementary innovation chains in order to reach major EU objectives.
Timeframe (months)	To follow EU budget periods	Minimum 3 years trial period	Minimum 3 years	Minimum 3 years to have an effect.
Funding sources	ESIF, regional and national public-private financing	ESIF, H2020, national and regional publi-private financing	EU Budget line, national and regional public-private financing	ESIF, H2020, national and regional public-private financing
Targets / deliverables	Yearly flagship progress and sustainability report including fulfilment of set of indicators; Yearly flagship forum with minimum 100 participants;	At least 15 candidates, PhDs with specialization on innovative procurement within health.; At least 50 in job professionals have received supplementary education	At least 10 ideas have proven to be commercially sustainable within the trial period	At least 5 sustainable regional cluster initiatives after 3 years
Targets and Roadmap Actions				